to other oral hypoglycemic drugs in this class, in view of their close similarities in mode of action and chemical structure.

[49 FR 14331, Apr. 11, 1984]

§ 310.518 Drug products containing iron or iron salts.

Drug products containing elemental iron or iron salts as an active ingredient in solid oral dosage form, e.g., tablets or capsules shall meet the following requirements:

(a) *Packaging.* If the product contains 30 milligrams or more of iron per dosage unit, it shall be packaged in unit-dose packaging. ''Unit-dose packaging'' means a method of packaging a product into a nonreusable container designed to hold a single dosage unit intended for administration directly from that container, irrespective of whether the recommended dose is one or more than one of these units. The term ''dosage unit'' means the individual physical unit of the product, e.g., tablet or capsule. Iron-containing drugs that are subject to this regulation are also subject to child-resistant special packaging requirements in 16 CFR parts 1700, 1701, and 1702.

(b) *Temporary exemption.* (1) Drug products offered in solid oral dosage form (e.g., tablets or capsules), and containing 30 milligrams or more of iron per dosage unit, are exempt from the provisions of paragraph (a) of this section until January 15, 1998, if the sole source of iron in the drug product is carbonyl iron that meets the specifications of § 184.1375 of this chapter.

(2) If this temporary exemption is not extended or made permanent, such drug products shall be in compliance with the provisions of paragraph (a) of this section on or before July 15, 1998.

(c) *Labeling.* (1) The label of any drug in solid oral dosage form (e.g., tablets or capsules) that contains iron or iron salts for use as an iron source shall bear the following statement:

WARNING: Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6. Keep this product out of reach of children. In case of accidental overdose, call a doctor or poison control center immediately.

(2)(i) The warning statement required by paragraph (c)(1) of this section shall appear prominently and conspicuously on the information panel of the immediate container label.

(ii) If a drug product is packaged in unit-dose packaging, and if the immediate container bears labeling but not a label, the warning statement required by paragraph (c)(1) of this section shall appear prominently and conspicuously on the immediate container labeling in a way that maximizes the likelihood that the warning is intact until all of the dosage units to which it applies are used.

(3) Where the immediate container is not the retail package, the warning statement required by paragraph (c)(1) of this section shall also appear prominently and conspicuously on the information panel of the retail package label.

(4) The warning statement shall appear on any labeling that contains warnings.

(5) The warning statement required by paragraph (c)(1) of this section shall be set off in a box by use of hairlines.

(d) The iron-containing inert tablets supplied in monthly packages of oral contraceptives are categorically exempt from the requirements of paragraphs (a) and (c) of this section.

[62 FR 2250, Jan. 15, 1997; 62 FR 15111, Mar. 31, 1997]

§ 310.519 Drug products marketed as over-the-counter (OTC) daytime sedatives.

(a) Antihistamines, bromides, and scopolamine compounds, either singly or in combinations, have been marketed as ingredients in over-the-counter (OTC) drug products for use as daytime sedatives. The following claims have been made for daytime sedative products: ''occasional simple nervous tension,'' ''nervous irritability,'' ''nervous tension headache,'' ''simple nervousness due to common every day overwork and fatigue,'' ''a relaxed feeling,'' ''calming down and relaxing,'' ''gently soothe away the tension,'' ''calmative,'' ''resolving that irritability that ruins your day,'' ''helps you relax,'' ''restlessness,'' ''when you're under occasional stress . . . helps you work relaxed.'' Based on